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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/710,613	07/23/2004	Vladimir Khripach		4612

7590 01/10/2005

Mikhail Samusevich
7201 19 Ave
2 Floor
Brooklyn, NY 11204

EXAMINER	
HARLE, JENNIFER I	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/710,613	KHRIPACH ET AL.	
	Examiner	Art Unit	
	Jennifer I. Harle	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-7* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1 and 4 (as it pertains to claim 1), drawn to a method for decreasing cholesterol, low-density lipoprotein and triglyceride levels in blood under cholesterol-enriched and normal diet, which comprises administering to a mammal 24-epibrassinolide (EBI, a plant hormone of structural formula I belong to brassinosteroid series, in a daily does of 0.03-2000 micrograms per kilogram of body weight, classified in class 514, subclass 200.

II. Claim 2 and claim 4 (as it pertains to claim 2), drawn to a method for increasing high-density lipoprotein level in blood under cholesterol-enriched and normal diet, which comprises administering to a mammal 24-epibrassinolide I in a daily dose of 1-50 micrograms per kilogram of body weight, classified in class 514, subclass 200.

III. Claim 3 and claim 4 (as it pertains to claim 3), drawn to a method for increasing vitamin E and vitamin A levels in blood under cholesterol-enriched diet, which comprises administering to a mammal 24-epibrassinolide I in a daily dose of 1-50 micrograms per kilogram of body weight, classified in class 514, subclass 200.

IV. Claims 5-8, drawn to a pharmaceutical composition or food supplement or food supplement in a food product comprising a therapeutically effective amount of 24-epibrassinolide, classified in class 514, subclass 200.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I, provides a hypocholesterolemic effect, i.e. which can treat a variety of dieases, including Type I diabetes, see Diabetic Bar, Fedubiters, Sabinsa Corporation, 2000-2001, pp. 1-8, while invention III, increasing Vitamins E and A would provide for protecting many functions of the body, including helping the eyes adjust to the light changes, bone growth, tooth development, reproduction, cell division and gene expression, as Vitamin A deficiencies cause problems in these areas and Vitamin E is responsible for protecting Vitamin A, see J. Andersonn, and L. Young., Fat-Soluble Vitamins, Food and Nutrition Series, Health, March 2002, No. 9.315, pp. 1-4. See MPEP § 806.05(d).

3. Inventions I-III and IV are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be used with a materially different product, i.e. Fenufibers can be used to decrease cholesterol, low-density lipoproteins and triglyceride levels in blood under cholesterol-enriched and normal diets, see Diabetic Bar, Fedubiters, Sabinsa Corporation, 2000-2001, pp. 1-8, increasing high density lipoprotein levels in blood under cholesterol-enriched and normal diet can be used with a materially different product, i.e. change in diet and exercise and the same is true for a different

product with invention III, i.e. a change in diet or vitamin supplements – foods will increase vitamin E and vitamin A levels in blood under cholesterol-enriched diet.

4. Additionally, searching the inventions of groups I, II and III together would impose a serious search burden. In the instant case, the search of the method for decreasing cholesterol, LDL and triglyceride levels or increasing high-density lipoproteins or increasing HDL or increasing vitamin e and vitamin A levels are not coextensive. There is a search burden in the non-patent literature, as one would not utilize the same search strategies and synonyms to search these claims. There may be articles devoted to decreasing cholesterol but not increasing HDL or increasing Vitamin A and E may have totally independent journal articles. Searching, therefore is not coextensive.

5. Furthermore, the searching of groups I-III and IV together would impose serious search burden. In the instant case, there is a search burden in the structure search of the compound alone and in the non-patent literature, as one would not utilize the same search strategies and synonyms to search a pharmaceutical compound or food supplement that one would use to search the method claims. There may be articles devoted to the use of the compound as a pharmaceutical/food supplement but not necessarily for the specific methods. Searching therefore is not coextensive.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer I. Harle
Examiner
Art Unit 1654

January 3, 2005